

1. **FDA MEDICAL EQUIPMENT RECALLS AND ALERTS.** The following recalls are reported in accordance with AFMLL 2-95, page CE-4, and should be treated as directed modifications in accordance with that AFMLL and AFI 41-201, Chapter 2, Section D. If you possess any of these items and have not received recall notification, you should contact the manufacturer for recall instructions. Suspension is only required for Class I items. (FOM-P, Capt Paul J. Toth, DSN 343-7445)

**CLASS I RECALLS:** None.

**CLASS II RECALLS:**

**6515 NS**

**MDC 14278**

**PRODUCT**

**CODE**

**MANUFACTURER**

**RECALLED BY**

**DISTRIBUTION**

**QUANTITY**

**REASON**

**Scanners, Ultrasonic (Diagnostic)**

128XP Diagnostic Ultrasound Imaging System, Model 128XP with Rev. 27.122 and 27.125. Recall #Z-787-9.

Rev. 27 software with the OB calculations option are affected by this system.

Acuson Corporation, Mountain View, California.

Manufacturer, by letter dated February 16, 1999. Firm-initiated field correction ongoing.

Nationwide and Canada.

637 units were distributed.

There is a potential error condition related to OB Reports printed after diagnosis.

☐ None Present

☐ Action Taken \_\_\_\_\_

**6515 NS**

**MDC 13271, 14059, 10822**

**11757, 16602**

**PRODUCT**

**CODE**

**MANUFACTURER**

**RECALLED BY**

**DISTRIBUTION**

**QUANTITY**

**REASON**

**X-Ray Rad Units**

Integris Family of X-ray Controls and Generators, general purpose fluoroscopy, urology, cardiology and interventional studies:

a) Integris H 1000; b) Integris H 3000; c) Integris BH 3000; d) Integris HM 2000; e) Integris HM 3000; f) Integris H 5000F; g) Integris H 5000C; h) Integris BH 5000; i) PolyDiagnost H; j) Integris V 3000; k) Integris BV/BN 3000; l) Integris V 4000; m) Integris V 5000. Recall #Z-748/760-9.

See model numbers above.

Phillips Medical Systems, Shelton, Connecticut.

Manufacturer. FDA approved the firm's corrective action plan on April 6, 1999. Firm-initiated field correction ongoing.

Nationwide.

1,086 units were distributed.

The diagnostic X-ray devices were found defective under the Federal performance standard for diagnostic X-ray systems and their major components. The defect occurs when the system is driven to maximum EER and the source to image receptor distance (SID) is moved to a shorter distance while continuing to make exposures. In this manner of operation, the output may exceed 10 R/min because the software will not update the output until the exposure control is released. Therefore, the system is in violation of the EER limits of the standard (21 CFR 1020.32(d) and (e)).

☐ None Present

☐ Action Taken \_\_\_\_\_

6525 NS  
MDC 15944  
PRODUCT

**Cameras, Gamma**

Millennium VG Nuclear Medicine Scanner, Model 2200967; Varicam Nuclear Medicine Scanner, Models 100-3101-0605 and 100-3101-0308. Recall #Z-745/747-9-

CODE  
MANUFACTURER  
RECALLED BY

All serial numbers.  
Elscint Ltd., Haifa, Israel.  
General Electric Medical System, Waukesha, Wisconsin, by instructions To replace the lateral gear box on February 20, 1999. Firm-initiated field Correction ongoing.

DISTRIBUTION  
QUANTITY  
REASON

Nationwide and international.  
187 units were distributed.  
Excessive wear of the lateral motion gears was found on several Varicam/Millennium VG Systems. Failure of a lateral motion gear Could allow the detector head to move/fall down without operator control  
☐ None Present  
☐ Action Taken \_\_\_\_\_

**2. DRUG/SUPPLY PRODUCT RECALLS AND MEDICAL INFORMATION.** The Food and Drug Administration (FDA) advises that the drug products listed below were recalled by the manufacturers or distributors concerned. The FDA has classified these recalls as follows:

**CLASS I:** A situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious, adverse health consequences or death.

**CLASS II:** A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

**CLASS III:** A situation in which the use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Most of these items are nonstandard, and the possibility exists that medical activities may have purchased them locally. There is also a possibility that some of these items have NSNs assigned and may have been reported in earlier Q.A. messages. Activities having quantities of these items on hand will immediately suspend the materiel from issue and use. CONUS activities will contact the nearest office of the respective manufacturer or distributor for disposition instructions. OVERSEAS activities will report quantities suspended to AFMLO/FOM-P no later than **4 Jun 99** for disposition instructions. They should include nomenclature; lot number; manufacturer; quantity suspended; strength size; requisition; and DPSC purchase order number, contract number, and stock record account number (SRAN). (FOM-P), **Bonnie Phillips DSN (343-4170)**

**CLASS I RECALLS:**

NSN  
PRODUCT

6505 Nonstandard  
GH Release Oral Liquid (2-(3H)- Furanone dihydro), OTC in 32 fluid ounce bottles. Recall #D-185-9.

CODE  
MANUFACTURER  
RECALLED BY

All lot codes.  
Phillips Pharmatech Labs, Inc., Largo, Florida.  
Oxygen Performance, Inc., also known as FURY, Clearwater, Florida, by letters on February 1 and 22, 1999. Firm-initiated recall ongoing. See also FDA talk paper T99-5 dated January 21, 1999.

DISTRIBUTION  
QUANTITY  
REASON

California, Florida, Georgia, Alabama, Iowa.  
2,500 bottles were distributed.  
Product is an unapproved new drug.  
☐ None Present  
☐ Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT GH Revitalizer Oral Liquid (2-(3H)- Furanone dihydro), OTC in 32 fluid ounce bottles, labeled for use for bodybuilding and sleep purposes. Recall #D-186-9.  
  
CODE All lot codes.  
MANUFACTURER GH Revitalizer, also known as HI-IR Industries, Orange Park, Florida.  
  
RECALLED BY Manufacturer, by letter dated February 9, 1999. Firm-initiated recall ongoing. See also FDA talk paper T99-5 dated January 21, 1999.  
  
DISTRIBUTION Nationwide.  
QUANTITY Approximately 3,600 bottles were distributed; firm estimates none remains on the market.  
  
REASON Product is an unapproved new drug.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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**CLASS II RECALLS:**

NSN 6505 Nonstandard  
PRODUCT Heparin Sodium Injection, USP, 1000 units/mL, in 5mL ampul, for IV or SC use, Rx anticoagulant. NDC #0209-4220-14. Recall #D-156-9.  
  
CODE Lot #9703043 EXP 03/2000.  
MANUFACTURERq Marsam Pharmaceuticals, Inc., Cherry Hill, New Jersey.  
RECALLED BY Manufacturer, by letter on December 10, 1998. Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide.  
QUANTITY 19,925 units were distributed.  
REASON Particulate matter.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT Liothyronine Sodium, USP, bulk powder, sold in 500 mg, 1 gram, and 5 gram units, Rx for the treatment of hypothyroidism. NDC numbers: 38779-0031-0 (500 mg), 38779-0031-6 (1 g), 38779-0031-3 (5 g). Recall #D-157-9.  
  
CODE Lot #55007 EXP 06/00.  
MANUFACTURER Topchem S.R.L., Milano, Italy (bulk drug supplier).  
RECALLED BY Medisca, Inc., Plattsburgh, New York, by letter dated January 28, 1999. Firm-initiated recall ongoing.  
  
DISTRIBUTION Nationwide.  
QUANTITY 192.5 grams were distributed.  
REASON Mislabeling - The product is Levothyroxine Sodium, not Liothyronine Sodium as labeled.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6505 Nonstandard  
PRODUCT Fortaz ADD-Vantage Vials (Ceftazidime for injection) 1 g, Rx indicated for the treatment of patients with infections caused by susceptible strains of the designated organisms for various diseases.  
  
CODE Recall #D-168-9.  
Lot numbers: B8419AA and B8769AF.

MANUFACTURER RECALLED BY	Glaxo Wellcome, Inc., United Kingdom. Glaxo Wellcome, Inc., Zebulon, North Carolina, by letter dated March 15, 1999. Firm-initiated recall ongoing.
DISTRIBUTION QUANTITY REASON	Nationwide. 2,178 units of lot B8419AA and 669 units of lot B8769AF were distributed. Lack of assurance of sterility (process validation failure-media simulation). <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Lyophilized Rx antibiotics for injection packaged in single dose ADD-Vantage vials, for use only with ADD-Vantage Flexible Diluent Containers: a) Cefazolin for Injection (lyophilized), Equivalent to 1-gram cefazolin, For I.V. Infusion only, Single dose ADD-Vantage Vial, NDC #0074-4732-03; b) Tazicef, Ceftazidime for Injection, Equivalent to 2 grams ceftazidime, For I.V. Infusion Only, Single dose ADD-Vantage Vial. NDC#0007-5091-01. Recall #D-169/170-9.
CODE	Lot numbers: a) 43-002-DA EXP 7/1/00; b) 43-003-DA EXP 7/1/00.
MANUFACTURER RECALLED BY	SmithKline Beecham, Conshohocken, Pennsylvania. Abbott Laboratories, Abbott Park, Illinois, by letter on March 26, 1999. Firm-initiated recall ongoing.
DISTRIBUTION QUANTITY	Nationwide. a) 73,825 vials; b) 6,000 vials were distributed, with firm estimating that 1,500 vials of Cefazolin and 1,000 vials of Tazicef remaining on market at time of recall initiation.
REASON	Lack of assurance of sterility. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Goldline brand Genatap Liquid, Antihistamine/Nasal Decongestant (each 15mL contains brompheniramine maleate 2 mg/phenylpropanolamine hydrochloride 12.5 mg), in 4 fluid ounce bottles, Rx. NDC #0182-2000-37. Recall #D-172-9.
CODE	Lot #9A05 EXP 1/2001.
MANUFACTURER RECALLED BY	Bio-Pharm, Inc., Levittown, Pennsylvania. Zenith Goldline Pharmaceuticals, Inc., Miami, Florida, by telephone on March 10-11, 1999, followed by letter dated March 11, 1999. Firm-initiated recall ongoing.
DISTRIBUTION QUANTITY	Nationwide. 2,678 bottles were distributed; firm estimated that 2,018 bottles remained on market at time of recall initiation.
REASON	Mislabeling - The immediate bottle label is incorrect, indicating the product to be Genahist Liquid (Diphenhydramine HCl). The holding carton is correctly labeled as Genatap liquid and the product in the bottle is Genatap. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____ _____
NSN PRODUCT	6505 Nonstandard Tutoplast Process Dura Mater, either under the Pfrimmer-Viggo or

Biodynamics International label, all sizes. This tissue product is a solvent dehydrated, gamma-irradiated preserved human dura mater, indicated for use in neurosurgical applications.  
Recall #Z-800-9.

CODE All sizes and all lots which bear an expiration date before April 1999.

MANUFACTURER Tutogen Medical US, Inc., formerly known as Biodynamics International US, Inc., Alachua, Florida.

RECALLED BY Manufacturer, by letter faxed on March 12, 1999. Firm-initiated recall ongoing.

DISTRIBUTION New Hampshire, Florida, California, Pennsylvania, Minnesota, Iowa, Ohio, Utah, Oregon, Michigan, Maryland, Texas, Arizona, Tennessee, Illinois, New York, Colorado, Washington state.

QUANTITY Undetermined.

REASON Patients may potentially contract Creutzfeld-Jacob Disease (CJD) from an implanted piece of dura mater contaminated with the CJD prions. The CJD can be due to inadequate donor screening and/or handling procedures by the German firm Pfrimmer-Viggo.  
[ ] None Present  
[ ] Action Taken \_\_\_\_\_

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NSN 6515 Nonstandard

PRODUCT Accutemp Disposable Battery Operated hand held Cauteries.  
Recall #Z-781/782-9.

CODE Catalog # 84-44000, Lot Nos. 14358100, 16313200 and 16644100  
Catalog #84-42000, Lot No. 14507500(Letters sent 1/29/99)  
Expanded lot numbers for recall (letters sent out on March 24, 1999)

Catalog Nos.	Lot Nos.
8442000	16133500
8442000	16676700
8442000	16724700
8442000	16724900
8442000	16751000
8442000	16896000
8442000	16896100
8442000	16896200
8442000	16896300
8442000	16958600
8442000	16958700
8442000	16958800
8442000	17080400
8442000	17080500
8442000	17080600
8442000	17080700
8442000	17119400
8442000	17150500
8442000	17150700
8442000	17150800
8442000	17362300
8442000	17421100
8442000	17617800
8442000	17625400
8442000	17625500
8442000	17744200
8443000	16436500

	8443000	16620600
	8443000	16620700
	8443000	16644200
	8443000	16644300
	8443000	16896600
	8443000	16896700
	8443000	16896900
	8443000	17080800
	8443000	17080900
	8444000	14012400
	8444000	16308500
	8444000	16644100
	8444000	16897000
	8445000	14696800
	8445000	16264100
	8445000	16388900
	8445000	16436600
	8445000	16511600
	8445000	16897100
	8446000	13053000
	8446000	16436700
	8446000	16593500
	8446000	16898900.
MANUFACTURER	Xomed, Inc., Jacksonville, Florida.	
RECALLED BY	Manufacturer, by letter on January 29, 1999, and March 24, 1999.	
	Firm-initiated recall ongoing.	
DISTRIBUTION	Nationwide.	
QUANTITY	11,881 boxes were distributed.	
REASON	Sterility barrier (packaging) may be open thereby compromising sterility.	
	[ ] None Present	
	[ ] Action Taken _____	
	_____	
NSN	6515 Nonstandard	
PRODUCT	EndoSonics Oracle MegaSonics 5-64 PTCA Catheter, indicated for percutaneous angioplasty to reduce coronary stenosis and improve perfusion: Model numbers 35825, 35830, 35835, 35840.	
	Recall #Z-783/786-9.	
CODE	Lot Numbers: 011999 and 012699.	
MANUFACTURER	EndoSonic Corporation, Rancho Cordova, California.	
RECALLED BY	Manufacturer, by telephone or by visit on March 15, 1999, and by letter on March 19, 1999. Firm-initiated recall ongoing.	
DISTRIBUTION	Nationwide.	
QUANTITY	250 units were distributed.	
REASON	Failure of the balloon to meet the rated burst pressure as labeled.	
	[ ] None Present	
	[ ] Action Taken _____	
	_____	
NSN	6515 Nonstandard	
PRODUCT	InstaTrak Straight Aspirators, Cat.No. ENT-100AS	
	InstaTrak 90 Degree Aspirator, Cat. No. ENT-101AM	
	InstaTrak 7 French Aspirator, Cat. No. ENT-100AS-P	
	The aspirators are accessories used with the InstaTrak System.	
	They are disposable hand-held instruments used as a single use	

CODE	aspiration as well as localization device. Model InstaTrak Straight Aspirators, Cat.No. ENT-100AS InstaTrak 90 Degree Aspirator, Cat. No. ENT-101AM InstaTrak 7 French Aspirator, Cat. No. ENT-100AS-P. Recall #Z-788/790-9.
MANUFACTURER	InstaTrak Straight Aspirator, Lot #'s: JAZ8270, JAZ8301, JAZ8334, JAZ8338
RECALLED BY	InstaTrak 90 Degree Aspirator, Lot #: JAZ8288
DISTRIBUTION	InstaTrak 7 French Aspirator, Lot #: JAZ8350
QUANTITY	Visualization Technology, Inc., Wilmington, Massachusetts.
REASON	Manufacturer, by letter on March 31, 1998. Firm-initiated recall ongoing. Nationwide, Egypt, Germany. 3,890 units were distributed. Outer pouch has incomplete seal compromising the sterility of the inner pouch. [ ] None Present [ ] Action Taken _____

**CLASS III RECALLS:**

NSN	6505 Nonstandard
PRODUCT	Pediacare brand OTC products for pediatric use. Labels for the first five products listed may state either McNeil Consumer Products Company Division of McNeil-PPC, Inc, or Marketed by Pharmacia & Upjohn Consumer Healthcare. The labels for the last two products listed state Marketed by Pharmacia & Upjohn Consumer Healthcare: a) Pedia Care Cough-Cold liquid (Each 5 mL contains pseudoephedrine hydrochloride 15 mg, chlorpheniramine maleate 1 mg, and dextromethorphan hydrobromide 5 mg), in 4 fluid ounce bottles; b) Pedia Care Cough-Cold Chewables (Each tablets contains pseudoephedrine hydrochloride 15 mg, chlorpheniramine maleate 1 mg, and dextromethorphan hydrobromide 5 mg), 16 tablets; c) Pedia Care NightRest Cough-Cold liquid (Each 5 mL contains pseudoephedrine hydrochloride 15 mg, chlorpheniramine maleate 1 mg, and dextromethorphan hydrobromide 7.5 mg), in 4 fluid ounce bottles; d) Pedia Care Infants' Drops Decongestant (Each 0.8mL (dropperful) contains pseudoephedrine hydrochloride 7.5 mg), in 1/2 fluid ounce (15mL) bottles; e) Pedia Care Infants' Drops Decongestant Plus Cough (Each 0.8mL (dropperful) contains pseudoephedrine hydrochloride 7.5 mg and dextromethorphan hydrobromide 2.5 mg)), in 1/2 fluid ounce (15mL) bottles; f) Pedia Care Fever liquid , Ibuprofen Oral Suspension, 100 mg per 5 mL (teaspoon), in 4 fluid ounce bottles; g) Pedia Care Fever drops, Ibuprofen Oral Suspension, 50 mg per 1.25 mL (dropperful), in 1/2 fluid ounce bottles. Recall #D-158/164-9.
CODE	All lots at retail with coupons attached.
MANUFACTURER	Parmacia & Upjohn, Kalamazoo, Michigan.
RECALLED BY	Manufacturer, by letter dated February 9, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Nationwide.
QUANTITY	419,000 packages were distributed.
REASON	Mislabeled - Some units are overlabeled with an incorrect peel off coupon. [ ] None Present [ ] Action Taken _____

NSN	6505 Nonstandard
PRODUCT	Bidex Tablets (Guaifenesin 800 mg) in 100 tablet bottles, Rx indicated for the temporary relief of coughs associated with respiratory tract infections, and related conditions such as pharyngitis, bronchitis, and asthma. NDC #45985-637-01. Recall #D-165-9.
CODE	Lot #J980755A.
MANUFACTURER	Mikart, Inc., Atlanta, Georgia.
RECALLED BY	Manufacturer, by letters on March 10 and 24, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Alabama, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Missouri, Nevada, North Carolina, Pennsylvania, Tennessee, Texas, Virginia.
QUANTITY	2,910 bottles were distributed.
REASON	Foreign particles - Carbon from raw material filtering. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____
NSN	6505 Nonstandard
PRODUCT	Duratuss G (Guaifenesin 1200 mg) in 500 tablet, bottles, indicated for the temporary relief of coughs associated with respiratory tract infections, and related conditions such as pharyngitis, bronchitis, and asthma. NDC #50474-620-50. Recall #D-166-9.
CODE	Lot #J980725A.
MANUFACTURER	Mikart, Inc., Atlanta, Georgia.
RECALLED BY	Manufacturer, by letter on March 10, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	Georgia.
QUANTITY	1,080 bottles were distributed.
REASON	Foreign particles - Carbon from raw material filtering. <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____
NSN	6505 Nonstandard
PRODUCT	Myleran Tablets (busulfan), 2 mg, in 25 tablet bottles, indicated for the palliative treatment of chronic myelogenous leukemia. Recall #D-167-9.
CODE	Lot #8G1422.
MANUFACTURER	Glaxo Wellcome, Inc., Zebulon, North Carolina.
RECALLED BY	Manufacturer, by letter on February 24, 1999.
DISTRIBUTION	Nationwide.
QUANTITY	8,426 units were shipped.
REASON	Subpotent (stability). <input type="checkbox"/> None Present <input type="checkbox"/> Action Taken _____
NSN	6505 Nonstandard
PRODUCT	Testoderm TTS, Testosterone Transdermal Patch System, 5 mg, 30 patches individually pouched, Rx for the controlled delivery of testosterone by means of a once-daily application of a transdermal system and is indicated for replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.
	NDC #17314-4717-3. Recall #D-171-9.
CODE	Lot #193473 EXP 12/99.
MANUFACTURER	ALZA Corporation, Vacaville, California.
RECALLED BY	Manufacturer, by letter dated March 15, 1999. Firm-initiated recall



DISTRIBUTION	ongoing.
QUANTITY	Nationwide.
REASON	81,000 systems were distributed.
	Stability - Product may not maintain ethanol levels within specification prior to expiry date (pouch seal defect).
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____
NSN	6505 Nonstandard
PRODUCT	Red Blood Cells. Recall #B-648-9.
CODE	Unit #16339-4110.
MANUFACTURER	Blood Systems, Inc., Jackson, Mississippi.
RECALLED BY	Blood Systems, Inc., Scottsdale, Arizona, by telephone on October 13, 1997, and by letter dated October 21, 1997. Firm-initiated recall ongoing.
DISTRIBUTION	Mississippi.
QUANTITY	1 unit was distributed.
REASON	Blood product was not refrigerated within eight hours of collection.
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____
NSN	6505 Nonstandard
PRODUCT	Liothyronine Sodium, USP, bulk powder, Rx, packaged in 250 mg, 1g, and 5g units, for further manufacture or prescription compounding by pharmacies. Recall #D-187-9.
CODE	Lot numbers: ML0014, NJ0033, NF0248, and NF0301.
MANUFACTURER	Medisca, Inc., Plattsburgh, New York (domestic supplier bulk drug); Topchem S.R.L., Milano, Italy (foreign bulk drug supplier).
RECALLED BY	Spectrum Quality Products, Gardena, California, by certified mail and telephone beginning March 9, 1999. Firm-initiated recall ongoing.
DISTRIBUTION	California, Connecticut, Idaho, Illinois, Indiana, Louisiana, Maryland, Montana, New Mexico, New York, Texas, Utah, Wisconsin.
QUANTITY	13 250-mg bottles; 11 1-g bottles; 2 5-g bottles were distributed.
REASON	Misbranded - Product is actually levothyroxine not liothyronine sodium as labeled
	<input type="checkbox"/> None Present
	<input type="checkbox"/> Action Taken _____
NSN	6515 Nonstandard
PRODUCT	Extension Set used with the Quantum PD Night Exchange System to extend the patient line on tubing sets with Easy-Lock compatible patient connectors:
	a) Catalog #5C4391P - English label; b) R5C4391 - European label.
	Recall #Z-797/798-9.
CODE	All lots.
MANUFACTURER	Baxter Healthcare Corporation, Mountain Home, Arkansas.
RECALLED BY	Baxter Healthcare Corporation, McGaw Park, Illinois, by letter dated March 25, 1999. Firm-initiated recall ongoing
DISTRIBUTION	Nationwide and international.
QUANTITY	496,000 units were distributed.
REASON	Sets were assembled with the blue clamp at the wrong end of the set.

☐ None Present  
☐ Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6515 Nonstandard  
PRODUCT Lubricated Latex Condoms, individually packaged for vending machines.  
Condoms may have the following brands on the plastic wrapper inside  
the cardboard display pack: Temptation, Pure Gold, Pure Platinum,  
and Sunrise.  
Recall #Z-799-9.  
CODE All condoms with the EXP 5/02.  
MANUFACTURER Hankook Latex Gongup Company, Ltd., Churchon, Kangwon DO, KS200-160,  
Korea.  
RECALLED BY Vend America, Inc. (V.A.I.), Lake Bluff, Illinois, by visit on March 11,  
1999. Firm-initiated recall ongoing.  
DISTRIBUTION Indiana, Illinois, Wisconsin.  
QUANTITY 3,600 units were distributed.  
REASON Outer packages has an extended expiration date.  
☐ None Present  
☐ Action Taken \_\_\_\_\_  
\_\_\_\_\_

NSN 6550 Nonstandard  
PRODUCT Abbott TestPack Rotavirus and Abbott TestPack Rotavirus with Control,  
an in-vitro diagnostic enzyme immunoassay for the rapid detection of  
Rotavirus antigen from human fecal specimens:  
a) Abbott TestPack Rotavirus - 20 Tests,  
List No. 6896-16,;  
b) Abbott TestPack Rotavirus with Control, 20 Tests,  
List No. 6896-25. Recall Z-791/792-9.  
CODE Lot numbers: 49023M200 and 50406M100.  
MANUFACTURER Abbott Laboratories, North Chicago, Illinois.  
RECALLED BY Abbott Laboratories, Abbott Park, Illinois, by letter dated March 16, 1999.  
Firm-initiated recall ongoing.  
DISTRIBUTION Nationwide and international.  
QUANTITY 1,065 kits were distributed.  
REASON The Conjugate Reagent 3 vial dispenses drops which are too large and  
does not contain enough reagent to complete the 20 tests claimed in  
the label.  
☐ None Present  
☐ Action Taken \_\_\_\_\_  
\_\_\_\_\_